

The effects of homocysteine-lowering vitamin supplementation on migraine disability

Submission date 29/11/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/12/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/12/2007	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Lyn Griffiths

Contact details
Griffith University
Gold Coast campus
Gold Coast
Australia
9726
L.Griffiths@griffith.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives

Does vitamin therapy including folic acid reduce homocysteine and migraine disability, and is the effect dependent on MTHFR genotype?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was approved by the Griffith University Ethics Committee on 11 November 2005 (ref: 3425)

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Migraine with aura

Interventions

Daily B vitamin (B6, B9, B12) therapy vs placebo for 6 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Migraine disability, as measured using the Migraine Disability Assessment (MIDAS) score at baseline and 6 months.

Secondary outcome measures

1. Migraine frequency. Duration of follow-up: 6 months
2. Migraine pain: MIDAS pain score 1-10 (10 = most severe) at baseline and 6 months

Overall study start date

30/11/2006

Completion date

30/11/2007

Eligibility

Key inclusion criteria

1. Current diagnosis of regular migraine with aura attacks
2. >18 and <70 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Co-morbid vascular or neuropsychiatric disease
2. Pregnant
3. Currently taking B vitamins

Date of first enrolment

30/11/2006

Date of final enrolment

30/11/2007

Locations

Countries of recruitment

Australia

Study participating centre

Griffith University

Gold Coast

Australia

9726

Sponsor information

Organisation

Griffith University (Australia)

Sponsor details

c/o Prof Lyn Griffiths
Gold Coast campus
Griffith University Qld 4222
Gold Coast
Australia
9726
L.Griffiths@griffith.edu.au

Sponsor type

University/education

ROR

<https://ror.org/02sc3r913>

Funder(s)

Funder type

Research organisation

Funder Name

Brain Foundation of Australia

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration